Dena C. Sharp (State Bar No. 245869)
Adam E. Polk (State Bar No. 273000)
Nina R. Gliozzo (State Bar No. 333569)
GIRARD SHARP LLP
601 California Street, Suite 1400
San Francisco, CA 94108
Tel: (415) 981-4800
Fax: (415) 981-4846
dsharp@girardsharp.com
apolk@girardsharp.com
ngliozzo@girardsharp.com

Eric H. Gibbs (State Bar No. 178658)
Amy M. Zeman (State Bar No. 273100)
GIBBS LAW GROUP LLP
505 14th Street, Suite 1110
Oakland, CA 94612
Tel: (510) 350-9700
Fax: (510) 350-9701
ehg@classlawgroup.com
amz@classlawgroup.com

Adam B. Wolf (State Bar No. 215914)
Tracey B. Cowan (State Bar No. 250053)
PEIFFER WOLF CARR KANE & CONWAY, APLC
4 Embarcadero Center, Suite 1400
San Francisco, CA 94111
Tel: (415) 766-3545
Fax: (415) 402-0058
awolf@peifferwolf.com
tcowan@peifferwolf.com

Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE PACIFIC FERTILITY CENTER LITIGATION

This Document Relates to:
No. 3:18-cv-01586
(A.B., C.D., E.F., G.H., and I.J.)

Master Case No. 3:18-cv-01586-JSC

PLAINTIFFS' TRIAL BRIEF

Pretrial Conference: April 29, 2021
Trial Date: May 20, 2021
Judge: Hon. Jacqueline S. Corley
Place: Courtroom F, 15th Floor

Trial Date: May 20, 2021

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PRELIMINARY STATEMENT

In accordance with the Court's Pretrial Order No. 1 (ECF. No. 206), Plaintiffs' Trial Brief presents an overview of the key factual matters that will be addressed at trial, and discusses controlling law and relevant evidence with respect to Plaintiffs' causes of action against Defendant Chart Inc. ("Chart") and Chart's defenses.

FACTUAL OVERVIEW

Chart designs and manufactures vacuum-insulated storage tanks to maintain biological samples at cryogenic temperatures with a minimal loss of liquid nitrogen each day. In March 2018, a Chart tank at Pacific Fertility Center that contained thousands of human eggs and embryos catastrophically failed. The incident caused the tank, known as "Tank 4," to lose all or nearly all of its liquid nitrogen. Plaintiffs A.B. and C.D., E.F., G.H., and I.J. are fertility patients whose eggs and embryos were stored in Chart's tank and exposed to the uncontrolled rise in temperature. The evidence at trial will show that Chart is responsible for its tank losing vacuum and imploding, and that it should be held liable for manufacturing a defective product and failing to recall or retrofit its product before this incident.

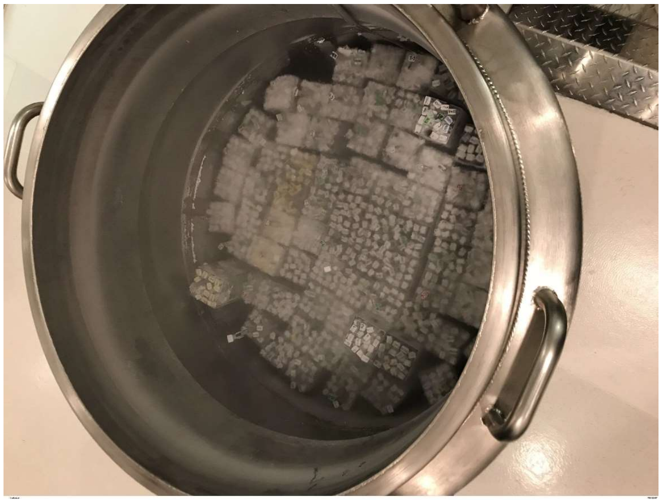
I. The March 4th Incident

On Sunday, March 4, 2018, the Laboratory Director at the Pacific Fertility Center, Joe Conaghan, discovered that the lid of one of the lab's cryopreservation tanks was stuck in place and there was condensation on the floor. (ECF No. 671-33 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 100, 115-116.) Tank 4 contained 2,500 embryos and 1,500 eggs from patients who had undergone egg-retrieval or IVF procedures. (ECF No. 671-34 (Pacific MSO 30(b)(6) and Romney Dep.) at 140; Trial Ex. 348 (MSO001982) at 1986.) Conaghan recognized something had gone seriously wrong. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 100.) Cryopreservation tanks depend on a vacuum layer to insulate frozen eggs and embryos in liquid nitrogen kept at constant temperature of -196° C. (Trial Ex. 90 (11/06/20 Wininger Report, as amended on 12/04/20 ("Wininger Am. Rep.")) at 8; ECF No. 674-22 (Chart 30(b)(6) and Brooks Dep.) at 20.) The condensation beneath the tank indicated the vacuum had failed and the tank had warmed, endangering the eggs and embryos it contained. (Chart 30(b)(6) and Brooks Dep. at 139-140.) Conaghan and other embryologists at PFC transferred the eggs and embryos to another tank, but the damage had already been done: ice crystals

form when cryopreserved samples are exposed to comparatively higher temperatures of between -150° C and -132° C, and the jagged edges of those crystals cause significant intracellular damage or cell death. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 119; ECF No. 673-04 (Wininger Dep.) at 68.)

The afternoon before the incident, one of PFC's embryologists had refilled Tank 4 before departing the clinic and confirmed that the tank had a sufficient quantity of liquid nitrogen. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 98-99; ECF No. 671-30 (Popwell Dep.) at 129-130.) Although a typical IVF tank consumes only about an inch to an inch-and-half of liquid nitrogen each day, PFC's practice was to ensure that its tanks contained at least 13 inches of liquid nitrogen at the close of business each day. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 61; Popwell Dep. at 41.) Embryologist Jean Popwell testified that on that particular Saturday afternoon, she filled Tank 4 up to the 14-inch mark on the tank's dipstick. (Popwell Dep. at 129.) An expert retained by Chart conducted a forensic investigation of PFC's digital lab records that confirmed her account: Tank 4's fill function was activated at 12:45 p.m., and the embryologist entered a measurement of 14 inches into PFC's lab monitoring system from one of the lab's iPads at approximately 2:39 p.m. (Trial Ex. 102 (11/06/20 Cauthen Report ("Cauthen Rep.") at 8-10; Trial Ex. 270 (CHART070093) at Record # 29848; ECF No. 673-12 (Cauthen Dep.) at 61-62; Trial Ex. 343 (MSO000310) at 360.) But when PFC's staff forcibly removed the tank's lid the following afternoon, Conaghan found that Tank 4's liquid nitrogen level had dropped to an inch at most. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 112-113.) Because Conaghan had activated the tank's fill function before he realized something was wrong and asked for help removing the lid, that inch of liquid nitrogen was most likely new liquid nitrogen—*i.e.*, Tank 4 lost all its liquid nitrogen in less than 24 hours. (*Id.* at 101, 112-113.)

After PFC staff finished removing eggs and embryos from Tank 4, they saw why the lid had been stuck in place: Tank 4's inner vessel had begun to implode. (*Id.* at 41-42, 114.) And in the hours after the tank was emptied, it continued to implode until it was a crumpled mass of stainless steel:



Normal Tank

Tank 4 After the Incident

II. Tank 4's vacuum insulation should have lasted 10 years and degraded gradually—giving PFC embryologists the warning signs they've been trained to look for.

Tank 4 was manufactured in January 2012 by Defendant Chart—a leading supplier of cryogenic containers for the IVF industry that claims to have "set the standard for storage of biological materials at low temperatures." (Trial Ex. 4 (Chart's Answers to RFA Set 4) at Answer No. 1; ECF No. 671-40 (Praxair 30(b)(6) Dep.) at 36; Trial Ex. 183 (CHART000007) at 9.) The tank was designed to maintain cryogenic temperatures with minimal evaporation of liquid nitrogen, which acts as a refrigerant for the biological material. (Trial Ex. 109 (11/06/20 Parrington Report ("Parrington Rep.") at 1.) Under California law, Chart may be held strictly liable if Tank 4 did not perform as safely as an ordinary consumer would have expected it to perform when used or misused in an intended or reasonably foreseeable way. *See* CACI 1203.

Plaintiffs' expert David Wininger opines that Tank 4 failed to perform as safely as he and other regular users of cryogenic containers would have expected it to perform. (Wininger Dep. at 36; Wininger Am. Rep. at 14.) As Wininger explains in his expert report, ordinary users expect cryogenic containers to be capable of safely storing sensitive biological samples at cryogenic temperatures for a

minimum of 10 years. (*Id.* at 14.) As the container ages, its vacuum insulation is expected to gradually degrade, rather than suddenly fail. (*Id.* at 14; Trial Ex. 247 (CHART050770).) That gradual degradation eventually manifests in physical symptoms that the container is losing its ability to keep samples cold: the container will become cool to the touch, condensation or frost will appear on its outer walls, and it will need to be refilled more often. (Wininger Am. Rep. at 14-15.) No reasonable user expects that a cryogenic container's vacuum will degrade to the point the container needs to be replaced in less than 10 years, or that the vacuum will catastrophically fail causing 14 inches of liquid nitrogen to dissipate in less than 24 hours. (*Id.*)

Chart's own expert and documents support Wininger's opinions that the Tank 4 incident was unexpected. Grace Centola, an andrologist who works with cryogenic tanks on a regular basis, testified that "[t]he general expectation [for the tank's vacuum] is eight to ten years at least," and when the vacuum does fail, the expectation is that "it would fail gradually." (ECF No. 674-12 (Centola Dep.) at 46.) Chart tells consumers that its cryogenic containers have a "10-year life expectancy"; that continued use after this time is normal and acceptable; that "normal degradation … is to be expected as the freezer ages"; and that if after ten years the evaporation rate exceeds what the user finds acceptable, the container can be re-vacuumed or replaced. (Trial Ex. 247.) Chart has represented to regulators that "Chart vacuum-insulated vessels provide hold times of at least 7 DAYS," meaning it should take at least a week and often much longer before a Chart cryogenic tank loses all of its liquid nitrogen to evaporation. (Trial Ex. 192 (DFMECA) at BAT-0, PWR-0, PWR-10, CTL-0; *see also* ECF No. 675-00 (Junnier Dep.) at 72-73 (Chart vessels "can maintain LN2 and temperature for quite a while, for weeks on end").) According to Chart's service agents, if premature vacuum degradation occurs, the user will "see other symptoms … such as excessive frost (when not filling), frequent fills, and frost and condensation on the lower exterior of the freezer (not near the lid)." (Trial Ex. 234 (CHART034331).) And Chart's medical risk management team has assigned the possibility of a total vacuum loss like that suffered by Tank 4 to the lowest possible risk level: "So unlikely, occurrence not expected." (Trial Ex. 192 (DFMECA) at DEW-3, DEW-4, and Risk Estimation tab.)

Chart's reaction to other similar tank failures confirms that such incidents are not expected. When another of Chart's cryogenic containers—this one storing stem cells for the Royal London

Hospital—was found to have lost all liquid nitrogen, Chart claimed, "we haven't seen any similar incident before." (Trial Ex. 248 (CHART051322).) It informed regulatory authorities that its "[c]ryo vessels will not lose their performance in a quick way. It will take some time before all Nitrogen will be evaporated from the vessel completely." (*Id.*) And when two other Chart containers storing bone marrow suffered sudden vacuum failures, Chart's authorized distributor wrote, "Wow, I have never seen this before.... This is very serious and we don't want this to get around"; Chart agreed, calling the incident "definitely an unusual circumstance." (Trial Ex. 263 (CHART062204) at 211.)

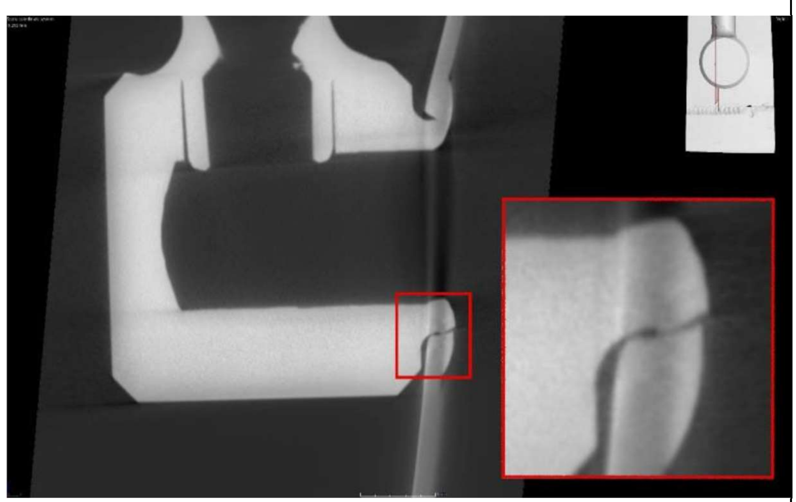
III. A cracked weld on the inside of Tank 4 caused the March 4th incident.

Post-mortem testing conducted by experts retained by Plaintiffs, Chart, and PFC disclosed why Tank 4's vacuum suddenly failed. (Trial Ex. 83 (11/06/20 Kasbekar Report, as amended on 11/30/20 ("Kasbekar Am. Rep.")) at 10-36.) The testing revealed a crack in a weld on the inside of the tank that connects the tank's fill tube to its inner vessel. (*Id.* at 16-19.) Chart's cryogenic tanks are manufactured with a metal tube that can be used to fill the tank with liquid nitrogen. (*Id.* at 20.) That tube runs from the top of the tank, down through the tank's vacuum insulation layer, and into the inner vessel near the bottom of the tank. The picture below was taken after Tank 4's outer vessel was removed; the red circle shows where its liquid nitrogen fill tube connected to the inner vessel through an elbow fitting:

Liquid nitrogen tube feeds into Tank 4's inner vessel

(*See id.* at 25.) The fill tube's elbow fitting was welded on the inside of Tank 4's inner vessel. That's the weld that cracked, as shown below. The image on the left is a close-up up the weld, with red dye indicating a crack, and the image on the right is a CT scan of the weld showing the through-wall crack that propagated through the entire thickness of the weld. (*Id.* at 19, 42.)

Close up of weld – red dye indicates a crack



CT scan of weld showing through-wall crack

The crack in Tank 4's interior weld allowed liquid nitrogen to seep from its inner vessel into its vacuum-insulation layer, where it was warmed by the surrounding laboratory air, transformed from liquid to gas, and expanded to almost 700 times its original volume. (*Id.* at 59-60.) The presence of so much nitrogen gas trapped between the tank's inner and outer vessels exerted substantial pressure, causing the inner vessel to implode. (*Id.*) More importantly, the presence of nitrogen gas destroyed the vacuum insulation that had been impeding heat transfer from the tank's room-temperature environment. Heat transfer ordinarily occurs when molecules bump into other nearby molecules and transfer some of their energy. When Tank 4's vacuum layer was still intact, it contained very few molecules, so heat transfer from the outside environment to Tank 4's inner vessel was minimal. But once that vacuum layer filled with high-pressure nitrogen gas, the number of molecules facilitating heat transfer greatly increased—and Tank 4 could no longer protect its contents from the outside air. (*See* Kasbekar Am. Rep. at 38.)

What happened to Tank 4 is exactly what Chart said would happen if an interior weld were to crack. The European Union's Medical Device Directive required Chart to identify each way that its cryogenic tanks can fail, and one of the failure modes disclosed by Chart in response involves a crack or leak at the weld joining the liquid nitrogen fill line to the tank's inner vessel—*i.e.*, the weld that cracked in Tank 4. If that weld cracked, Chart reported, the result would be: "Liquid draws into vacuum space, expanding rapidly and causing an inner vessel implosion, total vacuum loss. Loss of function of the freezer." (Trial Ex. 192.)

	A	B	C	D	E	F
1	**Design Failure Mode, Effects and Criticality Analysis**					
2	**CRYOGENIC FREEZERS: MVE, HECO, VARIO, CRYOSYSTEM FULL AUTO**					
3/4	ID#	Item	Item Function	Potential Design Failure Mode	Potential Cause of Design Failure Mode	Immed Effect of failure
47	DEW-3	Dewar- Annular lines	Fill line from the outer to inner vessel	Crack or leak	Weld Line Failure	Liquid draws into vacuum space, expanding rapidly and causing an inner vessel implosion, total vacuum loss. Loss of function of the freezer

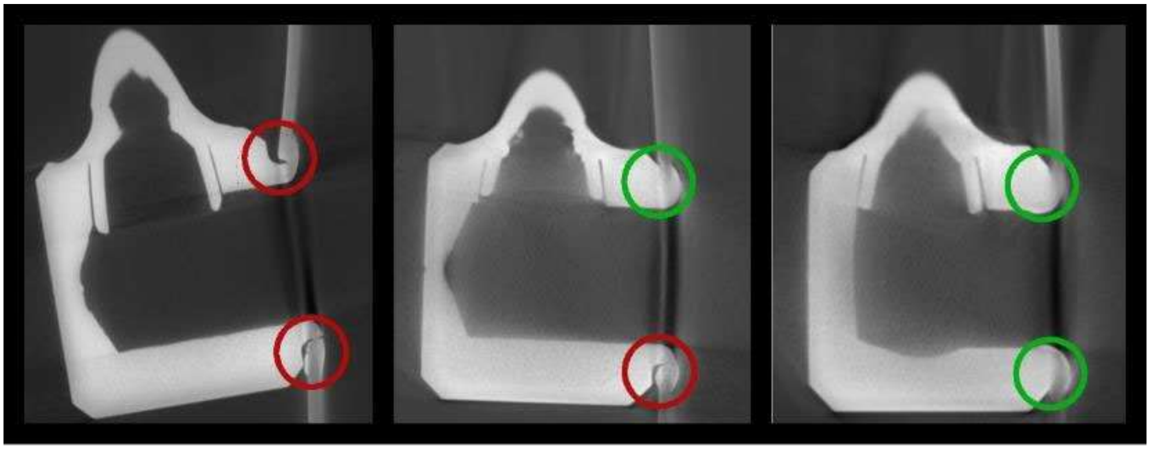
Chart's failure analysis: weld crack would cause total vacuum loss and an inner vessel implosion

Tank 4 was neither the first nor the last Chart freezer to suffer a total loss of vacuum and resulting inner vessel implosion. After other Chart containers experienced the same failure mode, an interior crack or leak on the inside of the tank was identified as the likely root cause. For example, when a cryogenic tank at Rutgers University lost vacuum overnight and imploded, damaging the biological samples stored inside, Chart's authorized distributor wrote that the implosion "is an obvious sign of an internal weld leak." (Trial Ex. 274 (CHART070695) at 696.) In another incident, a Chart tank filled with liquid nitrogen lost vacuum and imploded after being clamped to a forklift and moved to another building. Chart attributed that failure to a leak on the inside of the tank, likely created by the clamp: "the impact caused [nitrogen] gas to leak into the vacuum space and the immediate vaporization with a liquid to gas expansion caused a sudden increase in pressure that made the inner [vessel] collapse." (Trial Ex. 208 (CHART008310) at 310.)

IV. A manufacturing defect caused the cracked weld.

Post-mortem testing of Tank 4 further showed that the weld cracked because it was too thin and experienced a progressive fatigue fracture. (Kasbekar Am. Rep. at 44-45.) Chart's design specifications call for a full-penetration weld, which would completely fuse the fill tube's fitting to the tank's inner vessel wall and result in a weld at least as thick as the base metal. (Trial Ex. 272 (CHART070444); ECF No. 674-05 (Parrington Dep.) at 113-114, 139-140.) But Chart instead manufactured Tank 4 with a *partial*-penetration weld, which, instead of complete fusion, resulted in a thinner and weaker bridge between the two metal components. (Kasbekar Am. Rep. at 42-43, 53; Parrington Dep. at 113-114, 139-140.) The portion of the weld that ultimately failed was far thinner than the rest of the inner tank vessel and measured only about 0.005 inches—or only about as thick as a single human hair or single sheet of paper. (Kasbekar Am. Rep. at 42.)

The CT scans below illustrate the difference between (1) Tank 4's partial-penetration weld; (2) the weld on an exemplar Chart tank, which exhibits superior weld penetration; and (3) a proper full-penetration weld as called for in Chart's design specifications. The green circles indicate areas of complete weld penetration, and the red circles incomplete weld penetration.



Tank 4's weld *Another Chart tank's weld* *Proper weld*

(*Id.* at 52, 55.)

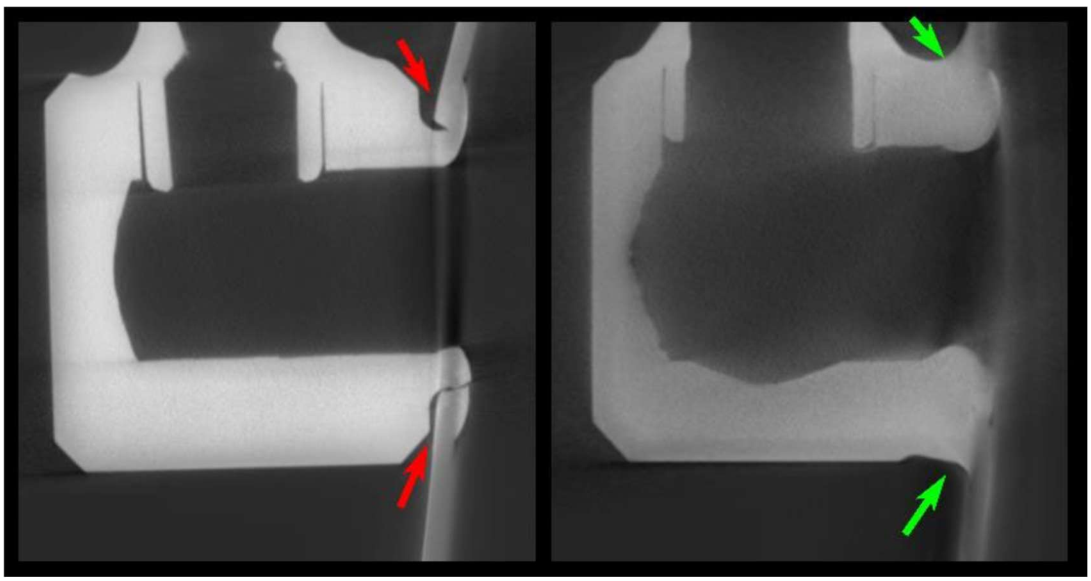
A full-penetration weld is necessary because the weld is exposed to repeated loading from thermal expansion and contraction throughout its lifetime. (*Id.* at 38-39, 44, 60-61.) Whenever the tank is filled with liquid nitrogen, the metal fill tube cools and contracts—pulling upward on the weld. (*Id.* at 38-39.) And, after the fill is complete, the upper portion of the fill tube warms and expands—pushing down on the weld. These repetitive stresses are akin to bending a paperclip back and forth until it breaks. (*Id.*) A full-penetration weld is sufficiently robust and durable to withstand these stresses over the life of the tank, but a weld as thin and incomplete as Tank 4's weld is not. The v-shaped notches seen in the CT images above are particularly problematic. They serve to concentrate the stresses in a very localized area of the weld—precisely where Tank 4's weld crack initiated. (*Id.*) Over time, that fatigue crack propagated through the entire thickness of the weld and ultimately caused it to fail. (*Id.* at 46, 59.)

V. Design defects also contributed to the cracked weld.

Elements of Tank 4's design also contributed to its failure. For one thing, the fitting Chart used to join Tank 4's fill tube to its inner vessel was not designed to sit flush against the inner vessel—although the fitting is flat, the inner vessel is curved. (*Id.* at 38-39.) Chart admits both that it would have been feasible to manufacture Tank 4 with a fitting that sat flush and that avoiding the physical mismatch presented no disadvantages. (Trial Ex. 4 at Answer No. 11; Trial Ex. 1 (Chart's Answers to ROG Set 6) at Answer No. 2.) The poor fit between Chart's fitting and Tank 4's inner vessel wall

contributed to the v-shaped stress concentrator that made Tank 4's weld susceptible to a fatigue fracture. (Kasbekar Am. Rep. at 38-39.) Even CT scans of a brand-new Chart tank show the beginnings of a fatigue crack due to this built-in stress concentrator. (*Id.* at 52-53, 56.)

Furthermore, Chart could have welded the fitting on *both* sides of the inner vessel instead of only on one side. The resulting weld would have been far more robust and would have eliminated the stress concentrator at the root of the weld, as shown in the CT images below. The red arrows point to the sharp stress concentrators at the root of Tank 4's weld, while the green arrows show how placing weld material in those notches eliminates the stress concentrator and ensures a complete fusion between the



1-sided weld design (Tank 4) *2-sided weld design*

fitting and inner vessel. (*Id.* at 53, 57, 61-63.) Given that this weld is subject to thermally induced stress throughout its lifetime, that stress concentrators make welds more susceptible to fatigue cracking, and that the consequences of weld failure are catastrophic, Chart should have employed this alternative two-sided weld design. (*Id.* at 53, 62.)

In addition, the manufacturing defect discussed in the previous section could also be construed as a design defect. Chart contends that even though its design specifications call for a full-penetration weld, Tank 4's partial-penetration weld conformed to its design and that it "intended a seal weld . . . with no minimum thickness." (Trial Ex. 4 at Answer Nos. 4, 6.) If Chart truly intended to use a partial-

penetration seal weld with no minimum thickness, that was an inappropriate design choice and one that caused Tank 4 to fail suddenly and without warning. (Kasbekar Am. Rep at 61-62.)

VI. Chart knew Tank 4's controller was defective but did not recall it.

Tank 4 was manufactured with a Chart TEC 3000 electronic controller that PFC was using to monitor the tank's conditions and sound alarms if the liquid nitrogen level dropped below 6 ½ inches. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 64-65, 72; Trial Ex. 270 at Record # 1783; ECF No. 671-31 (09/09/20 Conaghan Dep.) at 160; Trial Ex. 94 (11/06/20 Leaphart Report ("Leaphart Rep.")) at 25; *see* Trial Ex. 675-07 (02/06/20 Gustafson Dep.) at 165-166.) Had that controller been working at the time of the March 4th incident, it would have alerted PFC to the sudden vacuum failure in time to move Tank 4's eggs and embryos to the lab's backup tank before any damage was done. (Trial Ex. 101 (11/06/20 Centola Report ("Centola Rep.")) at 5; Trial Ex. 348 at 1988-1989; Pacific MSO 30(b)(6) and Romney Dep. at 194; Popwell Dep. at 87-88.) Even if no one had been in the IVF lab at the time, Tank 4's alarm system connected to a Sensaphone programmed to relay the alarm to PFC's embryologists, four of whom lived within 30 minutes of the IVF lab. (09/09/20 Conaghan Dep. at 54-56, 59-61; Trial Ex. 348 at 1988-1989.)

About two weeks before the March 4th incident, Tank 4's electronic controller lost its ability to accurately detect the tank's liquid nitrogen level and temperature: it continuously reported a liquid nitrogen level of 0 and a temperature of -273° C, even though the tank was full and the temperature of liquid nitrogen is -196° C. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 75; Pacific MSO 30(b)(6) and Romney Dep. at 111-112; Leaphart Rep. at 31.) These false readings caused the controller to repeatedly sound false alarms and continuously add liquid nitrogen to an already full tank. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 76-77, 187-189.) The only way Conaghan could stop the false alarms and continuous filling was to unplug the controller. (*Id.* at 79; Pacific MSO 30(b)(6) and Romney Dep. at 112-113; Trial Ex. 348 at 1986.) This was not the first time that one of the TEC 3000 controllers at PFC had malfunctioned and the Lab Director was hesitant to pay for yet another faulty controller. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 72-73.) While Conaghan troubleshot the controller in accordance with Chart's manual, and PFC looked into alternatives, the lab shifted to manual monitoring of Tank 4's liquid nitrogen levels. (10/09/19 Pacific MSO 30(b)(6) and Conaghan

Dep. at 78-79, 114-115; Trial Ex. 348 at 1986.)

Chart contends PFC should have made different choices when faced with constant false alarms and a controller that wouldn't stop filling an already full tank with liquid nitrogen. (11/20/20 Centola Supplemental Rep. ("Centola Supp. Rep.") at 4-5.) The extent to which PFC bears fault for the March 4th incident will be a central issue at trial, but one thing is certain: if Chart had recalled Tank 4's controller before the March 4th incident, PFC would not have been faced with a malfunctioning controller. Chart had known for over two years beforehand that its TEC 3000 controller was prone to suddenly stop working in the same way that Tank 4's controller stopped working. (Trial Ex. 675-08 (Gonzalez Dep.) at 33.) Chart even coined a name for this defect: "SN=0," because the controller's serial number would typically reset to 0 when it malfunctioned. (Trial Ex. 279 (EXTRON-000223) at 1; Trial Ex. 229 (CHART031817) at subject line.) As Chart noted after another IVF clinic's controller malfunctioned in May 2017, "SN=0 is usually accompanied by settings going haywire, level reading zero and both temps reading -273° C. Even if the controllers are functional afterward customers are not comfortable keeping the controllers installed." (Trial Ex. 201 (CHART004576).)

Chart estimates that a *hundred or more* TEC controllers malfunctioned as a result of the SN=0 defect, and its internal records suggest the actual number is higher. (ECF No. 671-53 (Chart 30(b)(6) and Bies Dep.) at 222-223; Trial Ex. 280 (EXTRON-000225) at 326; Trial Ex. 232 (CHART033664) at 665; Trial Ex. 209 (CHART008978); Trial Ex. 287 (EXTRON-004150); Trial Ex. 217 (CHART017944); Trial Ex. 239 (CHART038721) at 722.) Throughout 2015 and early 2016, customer after customer reported controller failures, Chart repeatedly demanded answers from its supplier, and Chart employees stressed that the company needed to "take action immediately." (Trial Ex. 239 at 722.)

- May 2015 – 5 controllers malfunctioned and "a handful of other customers that have reported similar issues" (Trial Ex. 280 at 326).
- June 2015 – "We need to know what is happening as we are beginning to experience an increased quantity of controllers that are [malfunctioning]" (*id.*).
- June 2015 – "the controllers (Tec3000) have very high return rates" (Trial Ex. 232 at 665).
- July 2015 – "we just lost a large quantity of freezer sales in Europe because of TEC3000 issue; Chart hierarchy needs an answer urgently why this is occurring" (Trial Ex. 209).

- Oct. 2015 – "Not sure what's happening here but we are receiving additional cases global wide relating to this issue; so it's not only overseas but also occurring in the USA" (Trial Ex. 287).
- Nov. 2015 – "[we] need to know that what is happening on these controllers can be controlled/contained to a minimum. … Even when we offer replacements they come up with the same issues" (Trial Ex. 217).
- Feb. 2016 – "We should plan to take action immediately as we have just experienced another 10 or so controllers that failed" (Trial Ex. 239 at 722).

Chart never did tell its customers about the SN=0 defect, though—even after it developed a fix. Chart determined that electrical interference in the TEC 3000's circuit board was likely to blame and developed a new touchscreen controller that "has these issues designed out of it at the board level." (Trial Ex. 197 (CHART002854) at 255; Junnier Dep. at 94-95.) As one of Chart's field service engineers explained, "It was our thought process that this touch screen controller would be the end – hopefully the end-all, be-all to fix these interference issues." (Junnier Dep. at 94-95.)

Chart released the new controller in May 2017 and succeeded in resolving the SN=0 defect. (Gonzalez Dep.) at 34) Chart also released retrofit kits that could be used on existing TEC 3000 controllers to resolve the SN=0 defect. (Junnier Dep. at 94-95; Trial Ex. 675-19 (Wade Dep.) at 128-130.) But Chart never told TEC 3000 users that they needed the retrofit to resolve a known defect. (Junnier Dep. at 94-96; Wade Dep. at 104, 129; Trial Ex. 272-02 (11/13/20 Pacific MSO 30(b)(6) and Conaghan Dep.) at 64-65.)

Chart knew that facilities like PFC were continuing to use defective TEC 3000 controllers, and, moreover, that they would often disable the controllers after they failed and switch to manual monitoring. (Trial Ex. 282 (EXTRON-000267); Chart 30(b)(6) and Brooks Dep.) at 165-166; Chart 30(b)(6) and Bies Dep. at 228; Junnier Dep. at 77-79.) But instead of retrofitting those defective controllers for free, or at least informing customers that the retrofit was available and would correct a known defect, Chart decided it would "try not to call attention to the issue with the customer." (Trial Ex. 223 (CHART028403) at 404.)

Chart was in a unique position to know just how dangerous it could be to operate one of its cryogenic tanks with a defective controller, but still did nothing. Ordinary users know that the vacuum

insulation in cryogenic tanks gradually degrades as the tank ages, and they know to keep a lookout for signs that the tank is losing vacuum. (Wininger Am. Rep. at 14.) But only Chart knew that an interior weld crack could cause an overnight vacuum failure in its cryogenic tanks. (Trial Ex. 192.) And only Chart knew that some of its tanks had experienced sudden vacuum failures and imploded. (Trial Ex. 263); Trial Ex. 274 at 696; Trial Ex. 208 at 310.) Chart also knew that many of its customers were IVF clinics or otherwise kept sensitive biological tissue in their Chart cryogenic containers, and that damage to those samples occurs at temperatures higher than -150° C. (Chart 30(b)(6) and Bies at 54-56; Trial Ex. 183 (CHART000007) at 9; Trial Ex. 219 (CHART20048); Trial Ex. 206 (CHART007923).) Armed with this knowledge, Chart had a responsibility to recall or retrofit its defective TEC 3000 controllers and ensure that any future sudden vacuum failures could be detected and addressed before the biological samples inside were damaged. Yet even now—after the March 4th incident damaged 2,500 frozen embryos and 1,500 frozen eggs—Chart still has not publicly disclosed the SN=0 defect or recalled the defective TEC 3000 electronic controllers used by medical facilities around the country. (Chart 30(b)(6) and Bies Dep. at 224.)

VII. The March 4th incident damaged Plaintiffs' eggs and embryos.

Plaintiffs had eggs and embryos stored in Tank 4 during the March 4th incident. As a result of Chart's defective weld and defective controller, those eggs and embryos were subjected to hazardous conditions and irreparably damaged. (Wininger Am. Rep. at 17-24.) The jagged ice crystals that form when frozen tissue is exposed to elevated temperatures caused cellular damage that greatly diminishes the likelihood that Plaintiffs' eggs and embryos will lead to a successful pregnancy. (*Id.* at 17.)

PFC cautions patients against using Tank 4 eggs and embryos, and when patients have tried, they have had dramatically lower success rates at every step of the IVF process. (*Id.* at 46; Trial Ex. 671-67 (Herbert Dep.) at 240. 244-247; Trial Ex. 315 at 62; Trial Ex. 105 (11/06/20 Jewell Report ("Jewell Rep.")) ¶¶ 30-44.) The chance of achieving a live birth from a frozen egg stored in Tank 4 is now 88% lower than it was before the March 4th incident, and the chance of achieving a live birth from a frozen embryo is now 72% lower:

	Pre-Incident	Post-Incident	Change
Chance of live birth per egg	9.6%	1.2%	-88%
Chance of live birth per embryo	47.8%	13.4%	-72%

(Wininger Am. Rep. ¶ 52.)

The cumulative impact on Plaintiffs' chances of having children using these eggs and embryos is significant. For example, Plaintiff I.J. froze 18 eggs and before the March 4th incident could have expected those eggs would yield an average of 2.7 children, with a 95% probability that she would give birth to at least one child. But after the March 4th incident, I.J. can now only expect an average of 0.2 births and only has a 19% probability of giving birth to at least one child.

			Pre-Incident		Post-Incident	
Plaintiff	# Stored	Egg age	Exp. Births	Chance of 1+	Exp. Births	Chance of 1+
A.B./C.D.	4 embryos	29	1.9	92%	0.5	44%
E.F.	9 eggs	34	1.4	77%	0.1	10%
G.H.	2 eggs	38	0.2	17%	0.0	2%
I.J.	18 eggs	34	2.7	95%	0.2	19%

(*Id.* ¶ 54.)

There are also good reasons to avoid using Tank 4 eggs or embryos altogether. (*Id.* ¶¶ 56-60.) As PFC's President explained, there is no information in the scientific or medical literature about the clinical or developmental consequences of using eggs or embryos that have been exposed to unsafe temperatures: "Can you imagine the experiment where you thaw a human embryo uncontrollably and then try to make a baby out of it? I don't think so." (Herbert Dep. at 240.) Plaintiffs' experts testified they would have serious reservations about using Tank 4 tissue in a frozen embryo transfer. (Wininger Am. Rep. ¶ 60; Trial Ex. 671-68 (11/15/19 Somkuti Dep.) at 100.) The low birthweights of children born from Tank 4 material present cause for concern. (Wininger Am. Rep. ¶¶ 59, 60; Trial Ex. 112 (11/06/20 Somkuti Report, as amended on 11/16/20 ("Somkuti Am. Rep."))

¶ 29.) Low birthweights are associated with increased risk for a variety of health problems throughout one's lifetime, and, of the babies born from Tank 4 material, 17% had low birthweights—about twice the normal rate. (Wininger Am. Rep. ¶ 59.)

VIII. The March 4th incident damaged Plaintiffs.

The impact of the March 4th incident on Plaintiffs' lives is difficult to overstate. Plaintiffs' eggs and embryos represented a substantial investment in their future, and one for which they paid a hefty price—emotionally and physically, as well as financially. Plaintiffs A.B. and C.D., who had four embryos in Tank 4, paid over $40,000 for their fertility treatments and associated costs, and Plaintiffs E.F., G.H., and I.J. each paid between $10,000 and $20,000 to retrieve and cryopreserve their eggs. (Trial Ex. 23 (A.B.'s Answers to Chart's ROGS) at Answer No. 24; Trial Ex. 26 (C.D.'s Answers to Chart's ROGS) at Answer No. 21; Trial Ex. 28 (E.F.'s Answers to Chart's ROGS) at Answer No. 21; Trial Ex. 30 (G.H.'s Answers to Chart's ROGS) at Answer No. 21; Trial Ex. 32 (I.J.'s Answers to Chart's ROGS) at Answer No. 21.1) The fertility treatments were stressful, invasive, and socially isolating. They required Plaintiffs to take daily hormone injections that cause soreness, bruising, nausea, bloating, fatigue, irritability, restlessness, depression, and anxiety. (Somkuti Am. Rep. ¶¶ 20, 26.) Plaintiff E.F. recalled "how scared I was of using the needles … how I was very irritable. [My boyfriend] and I got into a lot of fights. I was crying. I felt anxious." (Trial Ex. 93 (11/06/20 Grill Report, as amended on 11/19/20 ("Grill Am. Rep.") at 40.) In the days leading up to the attempted egg retrieval, Plaintiffs had to make multiple visits to a fertility specialist for transvaginal ultrasounds and hormone level evaluations. (Somkuti Am. Rep. ¶ 19.) The time commitments and uncertainty about whether their egg follicles would develop properly added to Plaintiffs' stress. (*E.g.*, Grill Am. Rep. at 23.) As did the egg retrieval itself, which is a surgical procedure that requires monitored anesthesia and the insertion of a hollow needle through the vaginal wall and into an ovary. (Somkuti Am. Rep. ¶ 21.)

After all that Plaintiffs had invested, it was devastating to learn that their eggs and embryos had been damaged in the March 4th incident and likely were no longer viable. As Plaintiffs A.B. and C.D. put it, "Those embryos were—were our family. Those were our children … you can't replace them." (Grill Am. Rep. at 49.) "The majority of our married life was spent creating those embryos—those were our world and they are gone." (*Id.* at 51.) To this day, A.B. is "always grieving the 'what if' … then

there's the clash with reality and I have to deal with the grief all over again." (*Id.* at 52.)

When Plaintiff E.F. heard about the tank failure, she "cried all morning." (*Id.* at 41.) Her mother came to stay with her because she was having nightmares and "screaming in my dreams." (*Id.*) She felt like "the rug was pulled out from underneath me and instead of feeling like I was building a future, I felt stuck in quick sand." (*Id.*)

Plaintiff G.H. recalls feeling numb when she first heard about the March 4th incident and described a "mourning process of the fact that I went through this, you know, somewhat traumatic experience to buy myself some insurance. And then that insurance was destroyed. … [I]t was emotional. It was sad." (*Id.* at 32.) She thinks about her lost eggs every day. (*Id.* at 33.) Due to low ovarian reserves, G.H. was only able to retrieve and cryopreserve two eggs, but as she put it, "Two eggs are more than zero. Those were my hope." (*Id.*)

Plaintiff I.J. was shocked and reacted with disbelief: "Why me? Why my tank?" (*Id.* at 25.) Two months later, she "had a miscarriage, and things got really bad after that." (*Id.*) She didn't know if the stress from the March 4th incident helped to cause that miscarriage, she started to doubt her fertility, and she "became frustrated and angry that [her] insurance policy was gone." (*Id.*) As I.J. put it, "I paid to have my eggs harvested and available for when I needed them, and they're gone. Those were my 34-year-old eggs, and I can't get them back. My options have been taken from me." (*Id.* at 26.)

LEGAL DISCUSSION

The evidence at trial will support a liability finding against Chart as to Plaintiffs' claims for strict liability based on a manufacturing and/or design defect, and for negligent failure to recall or retrofit. Chart's defenses attempting to shift the blame to PFC will fail under settled California law.

I. Plaintiffs' Claims

A. Strict Products Liability – Manufacturing and Design Defects

The evidence will show that Tank 4 had a manufacturing defect that was a substantial factor in causing the incident and, in turn, the harm Plaintiffs sustained. A product "has a manufacturing defect if it 'differs from the manufacturer's intended result or from other ostensibly identical units of the same product line.'" *Johnson v. United States Steel Corp.*, 240 Cal. App. 4th 22, 32 (2015) (quoting *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 429 (1978)); *see* CACI 1201. Chart's design drawings, employees, and

experts all confirm that Tank 4's specifications call for a full-penetration weld but that Tank 4 was manufactured differently, with only a partial-penetration weld. (Trial Ex. 272; ECF. No. 675-28 Ingram Dep. at 49-50, 66; 11/16/20 Parrington Dep. at 113-114, 139-140.) And, as shown above, a crack in Tank 4's weld is what destroyed its vacuum layer and caused the liquid nitrogen to disperse, damaging Plaintiffs' eggs and embryos. *See above*, Factual Overview, Section C. Chart's own documents identify this failure mode and discuss its previous catastrophic occurrences. (Trial Ex. 192 at DEW-3, DEW-4; Trial Ex. 274 at 696.) Similarly, Chart's expert admits that the crack in Tank 4 was a "through crack … that went from the inner vessel on one side through to the vacuum space on the back." (Trial Ex. 9 (Parrington Dep.) at 93.)

In addition, the jury may hold Chart strictly liable for a design defect by finding that Tank 4 did not perform as safely as its typical user would have expected it to perform when used in a reasonably foreseeable way. *See* CACI 1203; *In re Pac. Fertility Ctr. Litig.*, No. 18-CV-01586-JSC, 2021 WL 862463, at *2 (N.D. Cal. Mar. 8, 2021) (finding that "Chart has not shown as a matter of law that the consumer expectation test is inapplicable"). The evidence will show that Tank 4 failed to perform as safely as an ordinary user would have expected. *See above* Factual Overview, Section B. As Plaintiffs' expert points out, typical users of these storage tanks expect their vacuum insulation to degrade gradually, not all at once. (Wininger Dep. at 36-37, 55-56, 65-66; Wininger Am Rep. ¶¶ 37-42.) The way Tank 4 failed—losing its vacuum insulation overnight, consuming 14 inches of liquid nitrogen in less than 24 hours, and imploding—is beyond what any ordinary user of cryogenic tanks would reasonably expect, and this failure resulted in harm to Plaintiffs. (*Id.*; *see also* Centola Dep. at 46.)

The jury alternatively may hold Chart strictly liable for a design defect under the risk-benefit test. This test asks only whether the product's design was a substantial factor in causing plaintiffs' harm, and gives the defendant an opportunity to show that the benefits of its design outweigh the risks. *See* CACI 1204; *Demara v. The Raymond Corp.*, 13 Cal. App. 5th 545 (2017). First, as discussed above, the mismatch between the <u>flat</u> fitting that Chart used to attach the fill tube to the <u>curved</u> inner vessel contributed to the stress concentrator that led to the weld crack, and Chart admits there would have been no disadvantage from using an alternative design that ensured a closer fit of these important parts. (Trial Ex. 4 at Answer No. 11; Trial Ex. 1 at Answer No. 2.)

Second, Chart also could have ensured a stronger weld by welding the fitting on both sides of the inner vessel; the minimal cost of doing so is greatly outweighed by the consequences of catastrophic failure. *See above* Factual Overview, Section E. Given that this weld is constantly subjected to thermally induced stresses, that stress concentrators make welds more susceptible to fatigue cracking, and that weld failure in this setting has catastrophic effects, Chart should have used the two-sided weld design. (Kasbekar Am. Rep. at 53, 62.) Chart concedes, however, that it "intended a seal weld … with no minimum thickness." (Trial Ex. 4 at Answer No. 6.)

B. Negligent Failure to Recall or Retrofit

The evidence will further demonstrate Chart acted negligently by failing to recall or retrofit Tank 4's malfunctioning controller. *See* CACI 1223. Chart knew of the controller defect, and that it would result in dangerous conditions with foreseeable use, and even developed a replacement product. But Chart unreasonably failed to inform PFC of the need to replace the defective controller, which would have reinstated the alarm systems that would have avoided Plaintiffs' loss.

Evidence shows that numerous TEC 3000 controllers suffered from a defect that causes them to stop accurately monitoring liquid nitrogen levels, and that Chart had a name for this defect and knew it was important "to take action immediately," but failed to do so. (Trial Ex. 239 at 722; Trial Ex. 279 at 1; Trial Ex. 204 (CHART031817) at subject line.) Although Chart developed a replacement controller, it did not communicate to customers like PFC that were responsible for sensitive biological material that they needed to change to this safer design. (Trial Ex. 197 at 255; Trial Ex. 183 at 9; Junnier Dep. at 94-96; Wade Dep. at 104, 128-130; Gonzalez Dep. at 33-34); Chart 30(b)(6) and Bies at 54-56; 11/13/20 Pacific MSO 30(b)(6) and Conaghan Dep. at 64-65.) Analogously, the manufacturer in *Hernandez v. Badger Constr. Equip. Co.*, 28 Cal. App. 4th 1791 (1994), had addressed a known safety issue in newly manufactured products but decided not to retrofit the products it had already sold, such that "the jury could properly conclude [defendant] did not do 'everything reasonably within its power to prevent injury' to plaintiffs." *Id.* at 1828.

The jury also may conclude that Chart's failure to retrofit or recall the controller was a legal cause of the March 4th incident—it need not be the sole cause and its contribution need only be "more than negligible or theoretical." *Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 978 (1997); *see*

CACI 430, 431. Chart's electrical expert admits that Tank 4 manifested the symptoms of this "SN=0" controller defect, as did multiple witnesses who worked with the relevant tank controller at PFC. (ECF No. 675-30 (Leaphart Dep.) at 76; *e.g.*, 10/09/19 Pacific MSO 30(b)(6) and Conaghan at 74-77; 09/10/19 Pacific MSO 30(b)(6) and Romney at 111-112.) Predictably, the false alarms and continuous filling led PFC to simply unplug the controller and switch to manual monitoring of Tank 4's liquid nitrogen levels. (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep. at 79, 114-115; Pacific MSO 30(b)(6) and Romney Dep. at 112-113; Trial Ex. 348 at 1986.) A working controller would have alerted PFC staff that Tank 4's liquid nitrogen level had dropped below 6.5 inches and given them time to transfer Plaintiffs' eggs and embryos to a backup tank before they were irreversibly damaged. (Trial Ex. 270 at Record # 1783; 09/09/20 Conaghan Dep. at 54-56, 59-61, 160; Pacific MSO 30(b)(6) and Romney Dep. at 194; Popwell Dep. at 87-88; Trial Ex. 348 at 1988-1989.) PFC's deactivation of the controller does not negate Chart's negligence, as Chart knew that other customers did exactly that when confronted with SN=0 failures. (Trial Ex. 282 (EXTRON-000267)) *See also infra* Legal Discussion, Section II.

C. Damages

Upon a liability finding under any of these causes of action, the jury may award Plaintiffs compensatory damages. Their economic damages include the damage to their eggs or embryos, whose value may be established through other sources, including the expense of obtaining and cryopreserving the eggs and embryos; the time expended to obtain them; the difficulty that obtaining them entailed; their nature and character; and the use for which they were intended. *See United States v. CB & I Constructors, Inc.*, 685 F.3d 827, 837 (9th Cir. 2012); *Kimes v. Grosser*, 195 Cal. App. 4th 1556, 1560-62 (2011); *see above* Factual Overview, Sections G, H. Plaintiffs' past and future medical expenses are also recoverable. *See* CACI 3903A; *above* Factual Overview, Section H. And the jury may award Plaintiffs non-economic damages for their understandable shock, grief, and sorrow after this incident. *See* CACI 3905A; *above* Factual Overview, Section H.

In addition, the jury may determine that punitive damages against Chart are warranted based on its knowing disregard in failing to ensure the repair of its defective controller attached to the cryogenic storage tanks. *See* CACI 3946; *In re Pac. Fertility Ctr. Litig.*, 2021 WL 862463, at *4 (noting evidence

that may support a punitive damages entitlement indicating "Chart was aware of the defect, that it took no action to address the defect unless the issue was raised by a customer, and that it was aware that sudden changes in the liquid nitrogen level (which the controller should alert for) could cause damage and loss of function to the freezer.").

II. Chart's Defenses

Chart intends to point the finger at PFC at trial, asserting that PFC's conduct in relation to Tank 4 broke the chain of causation. But the defenses Chart has raised—superseding cause (CACI 432); sophisticated user (CACI 1244); and product misuse (CACI 1245)—are subject to the principle that Chart's "negligent conduct may combine with another factor to cause harm," so Chart "cannot avoid responsibility just because some other person, condition, or event was also a substantial factor in causing the plaintiff's harm." *Yanez v. Plummer*, 221 Cal. App. 4th 180, 187 (2013); *see* CACI No. 431. Therefore, for example, unless the jury finds PFC's conduct "so extreme as to be the sole cause of [Plaintiffs'] injury," *Perez v. VAS S.p.A.*, 188 Cal. App. 4th 658, 685 (2010), Chart's product misuse defense must fail. Chart thus cannot escape liability where both PFC's behavior after Chart's controller failed and the consequences of Chart's weak weld were foreseeable.

Chart's main defense "revolves around a determination of whether the … intervening cause, was foreseeable by the defendant or, if not foreseeable, whether it caused injury of a type which was foreseeable. If *either* of these questions is answered in the affirmative, then the defendant is *not* relieved from liability[.]" *Akins v. County of Sonoma*, 67 Cal. 2d 185, 199 (1967) (emphasis added). The evidence will show that Chart was aware that its customers, to avoid overfilling, were turning off the controller when it failed. Hence, Chart's superseding cause defense will fail because "both the intervening act and the results of that act must not be foreseeable" for the defense to succeed. *Chanda v. Federal Home Loans Corp.*, 215 Cal. App. 4th 746, 755-56 (2013) (citation omitted).

Chart knew that customers like PFC continued to use their tanks after the TEC 3000 controller failed and it knew why: customers expect that any loss in the tank's ability to maintain cryogenic temperatures will occur gradually because of normal degradation in the tanks' vacuum insulation—not suddenly and all at once. (Chart 30(b)(6) and Brooks Dep. at 165-166; Chart 30(b)(6) and Bies Dep. at 228; Trial Ex. 247.) Only Chart knew how dangerous it was to operate one of its tanks without a

controller, even temporarily. (Trial Ex. 192 at DEW-3, DEW-4; Trial Ex. 248; Trial Ex. 263.) Chart also knew that it was critical for Tank 4's controller to be replaced immediately, as sudden vacuum failures had been known to occur in Chart's cryogenic tanks housing biological material. (11/13/20 Pacific MSO 30(b)(6) and Conaghan Dep. at 64-65; Junnier Dep. at 94-95; Wade Dep. at 104, 128-130; Trial Ex. 192 at DEW-3, DEW-4.) By contrast, PFC neither knew nor had any reason to know, *see Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 71 (2008) (sophisticated user defense), that the problem was caused by a known defect in the TEC 3000 or that a ready fix was available, and reasonably expected that manual monitoring would be sufficient in the interim. (Pacific MSO and Romney Dep. at 114-115; 09/09/20 Conaghan Dep. at 19.) Moreover, as of March 4th, PFC had asked its supplier to resolve the controller problem but had not yet received a replacement. (Trial Ex. 404.) Under these circumstances, PFC's response to the controller malfunction cannot be deemed negligent at all, much less "highly extraordinary" or "extraordinarily negligent." *Stewart v. Cox*, 55 Cal. 2d 857, 864 (1961).

CONCLUSION

The foregoing Plaintiffs' Trial Brief is respectfully submitted.

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Respectfully submitted,

By: *__/s/ Amy M. Zeman__*

Eric H. Gibbs (State Bar No. 178658)
Amy M. Zeman (State Bar No. 273100)
GIBBS LAW GROUP LLP
505 14th Street, Suite 1110
Oakland, CA 94612
Tel: (510) 350-9700
ehg@classlawgroup.com
amz@classlawgroup.com

Dena C. Sharp (State Bar No. 245869)
Adam E. Polk (State Bar No. 273000)
Nina R. Gliozzo (State Bar No. 333569)
GIRARD SHARP LLP
601 California Street, Suite 1400
San Francisco, California 94108
Tel: (415) 981-4800
Fax: (415) 981-4846

dsharp@girardsharp.com
apolk@girardsharp.com
ngliozzo@girardsharp.com

Adam B. Wolf (State Bar No. 215914)
Tracey B. Cowan (State Bar No. 250053)
PEIFFER WOLF CARR KANE & CONWAY, APLC
4 Embarcadero Center, Suite 1400
San Francisco, CA 94111
Tel: (415) 766-3545
Fax: (415) 402-0058
awolf@peifferwolf.com
tcowan@peifferwolf.com

Counsel for Plaintiffs